

Appl. No. 09/991,209
Docket No. GC48-2

REMARKS

Status of the Application and Claim Amendments

With entry of the present amendment claims 3 – 12, 14, 15, 18, 19, 23, 25, 27 – 31, 32, 33, 75 and 77 – 83 are pending. Claims 3, 8, 9, 12, 14, 23, 25, 29, 32, and 75 have been amended and claims 80 – 83 are new. Claims 1, 2, 13, 16, 17, 20 – 22, 24, 26, 34 – 74 and 76 have been cancelled, without prejudice. Applicants reserve the right to file further continuation and/or divisional applications on the subject matter of any cancelled claim. New matter has not been introduced by the amendment. Applicants acknowledge the Examiner's statement that claims 3 - 7, 15, 18 -19, 30, 32, 33 and 76 are deemed to be free of the prior art.

Claim 3 has been amended as an independent claim and incorporates the elements of now cancelled claims 1 and 2. Claim 3 is directed to a transgenic plant which is a *Festuca*, *Lolium*, *Sorghum*, *Zea*, *Triticum*, *Avena* or *Poa* plant and the expression cassette includes a polynucleotide encoding an *Aspergillus niger* ferulic acid esterase FAE1 and a signal sequence that targets expression of the ferulic acid esterase to the endoplasmic reticulum, vacuole, apoplast or golgi apparatus.

Claims 4 – 12, 14, 15, 18, 19, 23, 25, 27, 28, 29, 30, 31, 33 and 80 - 83 depend from independent claim 3. Dependency has been changed for claims 8, 9, 12, 14, 23, 25, 29 and 33. These claims now dependent from claim 3 as opposed to claim 1. Claims 80 - 83 are new, and are directed to plants of *Lolium*, *Zea*, *Zea mays* and *Avena*, respectively.

Independent claim 75 has been amended to incorporate the limitation of now cancelled claim 76 and further *Sorghum*, *Triticum* and *Poa* plants have been omitted from the claim.

Rejection under 35 U.S.C. §112, first paragraph.

Claims 1- 12, 14 -15, 18 –19, 23, 25, 27-33, and 74 - 79 have been rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement.

Applicants maintain their position that one skilled in the art could isolate ferulic acid esterases and that ferulic acid esterases are known in the art. This statement is not

Appl. No. 09/991,209
Docket No. GC48-2

Applicants maintain their position that one skilled in the art could isolate ferulic acid esterases and that ferulic acid esterases are known in the art. This statement is not inconsistent with the teaching in the specification that only one FAE gene had been cloned (USP 6,368,833). Nevertheless to expedite prosecution of this application, both independent claims 3 and 74 have been amended to recite an *Aspergillus niger* ferulic acid esterase FAE1 encoding polynucleotide

The Examiner also states that while claims 1- 12, 14 -15, 18 -19, 23, 25, 27 - 33, and 74 - 79

"....are enabling for transgenic Festuca and Lolium comprising a polynucleotide encoding an FAE1 enzyme from Aspergillus of SEQ ID NO: 1 wherein the expression of the Aspergillus FAE1 is targeted to the vacuole, ER or apoplast, does not reasonably provide enablement for any grass plant comprising any FAE1 encoding polynucleotide from any organism."

As stated above, independent claims 3 and 74 recite an *Aspergillus niger* ferulic acid esterase FAE1 encoding polynucleotide and specific genera of transgenic plants.

Claim 1 has also been amended to include the element of a signal sequence that targets expression of the ferulic acid esterase to the endoplasmic reticulum, vacuole, apoplast or golgi apparatus.

Applicants contend that the pending claims fulfill the requirements of 35 U.S.C. §112, first paragraph and withdrawal of all rejections under this section is requested.

Rejection under 35 U.S.C. §102(b).

The Examiner has rejected claims 1, 2, 8, 14 and 23 as anticipated by Michelson et al. (US Pat. No. 6,143,543; the '543 patent). Applicants respectfully traverse this rejection.

As previously argued, the '543 Patent is directed to use of an FAE enzyme as an enzyme additive for treating plant material, foodstuffs, and feeds. The FAE is expressed preferably in a fungal host cell. While the disclosure does state that the enzyme may also be expressed in a plant and secreted by the plant. The teaching of the reference is focused on high levels of gene expression and use of plants as a source of FAE for improving feed or food after extraction. There is no teaching of targeted FAE expression

Appl. No. 09/991,209
Docket No. GC48-2

in a plant in which expression is targeted to certain plant cellular components and wherein FAE activity may be used for improving the digestibility of the plant.

Moreover, there is no teaching of a transgenic plant comprising a signal sequence which targets FAE expression to particular cell compartments which would result in cell wall modification in a controlled manner. The '543 Patent in general concerns the use of constitutive promoters, which are primarily non-plant promoters. The use of a constitutive promoter would result in high expression and hence accumulation of FAE which could prove to be lethal to a plant. At column 11, of the '543 Patent there is mention of plant promoters, such as the Amy 3 promoter. While this promoter may be an inducible promoter, the reference still lacks any suggestion of targeted cell compartment expression. Applicants assert the '543 Patent is not an enabling disclosure which includes each and every element as claimed by the instant claims.

Rejection under 35 U.S.C. §103.

The Examiner has also rejected claims 1, 2, 8 – 12, 14, 23, 25, 27 – 29, 31, 74, 75 and 77 - 79 as allegedly obvious over the combination of Michelson, *et al.* (US Pat. No. 6,143,543; the '543 patent) in view of Bartolome, *et al.* (Applied and Environmental Microbiology (1997) 63(1):208-212). Applicants respectfully traverse the rejection.

An essential requirement for a *prima facie* case of obviousness is whether a person skilled in the art would be motivated to modify the references to arrive at the claimed invention. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988) and *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

A *prima facie* case of obviousness requires the Examiner to cite to a combination of references which (a) suggests or motivates one of skill in the art to modify their teachings to yield the claimed invention, (b) discloses the elements of the claimed invention, and (c) provides a reasonable expectation of success should the claimed invention be carried out. Failure to establish any one of these requirements precludes a finding of a *prima facie* case of obviousness and, without more, entitles Applicants to withdrawal of the rejection of the claims in issue. See *e.g.*, *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990); and *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). Applicants urge that the Examiner has

Appl. No. 09/991,209
Docket No. GC48-2

failed to establish not one, but all three requirements.

The expression cassette as claimed by Applicants include not only an FAE encoding polynucleotide operably linked to a promoter but also a targeting sequence wherein expression in the plant is targeted to certain cell components.

While stable expression of FAE is an element of Applicant's invention it is the targeted expression of FAE. This is not taught or suggested by the '543 Patent alone or in combination with the secondary reference.

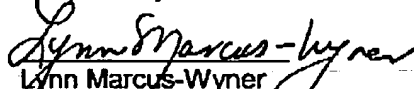
With respect to Bartolome *et al.*, there is no teaching regarding the recombinant expression of xylanase in plants. All Bartolome *et al.* provides is that the treatment of wheat and barley cell walls by exogenous FAE and xylanase, in combination, results in the release of certain dimers. As stated in the abstract,

"(We show that incubation of wheat and barley cell walls with ferulic acid esterase from *Aspergillus niger* (FAE-III) or *Pseudomonas fluorescens* (XylD), together with either xylanase I from *Aspergillus niger*, *Trichoderma viride* xylanase or xylanase from *Pseudomonas fluorescens* (XylA), leads to release of the ferulate dimer 5-5'diFA.....)"

Even if Bartolome *et al.* is combined with the '543 Patent there is no indication provided as to of how recombinant targeted expression of an FAE in grass plants could or even should be accomplished.

In light of the above amendments, as well as the remarks, Applicants believe the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7620.

Respectfully submitted,


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Date: June 3, 2005

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